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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/806, 400 03/30/01 SHOENFELD

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HM12/1001

EXAMINER

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ART UNIT	PAPER NUMBER
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1644

DATE MAILED:

10/01/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.

09/806,400

Applicant(s)

Shoenfeld et al.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on 8/10/2001

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-26 is/are pending in the application.

4a) Of the above, claim(s) 2-4, 8-11, 15-17, 21-24 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1, 5-7, 12-14, 18-20, 25, 26 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892)

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20)  Other: \_\_\_\_\_

1. Applicant's election of Group I and the species atherosclerosis in Paper No. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 2-4,8-11,15-17,21-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

3. Claims 1,5-7,12-14,18-20,25,26 are under consideration.

4. The first line of the specification should be amended to indicate that the instant application is a national stage filing under 35 USC 371 of PCT/IL99/00519 .

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1,5-7,12-14,18-20,25,26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "modified LDL" because it is unclear what this term means or encompasses. It has no art recognized meaning and the meaning of said term is not disclosed in the specification. Claims 7,12,20 and 25 are indefinite in that "active derivative" lacks antecedent basis in claim 1 (7,12) or 14 (20,25) respectively.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 1,5,7,12,14,18,20,25 are rejected under 35 U.S.C. 102(b) as being anticipated by Yesair (US Patent 4,874,7695).

Yesair teaches a composition for oral administration containing LPC (see column 5, last paragraph and Examples). The recitation of an intended use carries no patentable weight in the instant product claims (eg. 1,5,7,12). LPC is a derivative of LDL (see claim 12). LPC is also a derivative of Ox LDL (see specification, page 5, first complete paragraph). LPC is a modified LDL. The pharmaceutically acceptable carrier is the other lipids contained in the composition taught by Yesair (see column 5). Yesair teaches the in vivo administration of said composition (see Examples and column 13, last paragraph). It is an inherent property that administration of the claimed composition results in the method of claim 14, because the method taught by Yesair involves administration of the same compound (LPC) to the same population (eg. any individual, because it would be desirable to prevent atherosclerosis in any individual).

10. Claims 1,5-7,12,13 are rejected under 35 U.S.C. 102(e) as being anticipated by Witztum et al. (US Patent 6,225,070).

Witztum et al. teach a composition containing MDA-LPL or oxidized LPL or Acetyl-LDL in PBS (see column 18). The recitation of an intended use carries no patentable weight in the instant product claims. The pharmaceutically acceptable carrier is PBS (see column 18, lines 55 and 56).

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1,5-7,12,14,18-20,25,26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strober et al. in view of Hansson et al., Resch et al. and Sima et al.

Strober et al. teach compositions of autoimmune antigens and the use of said compositions to treat autoimmune disease (see abstract). Strober et al. teach that the orally administered composition contains autoantigen and a pharmaceutically acceptable carrier (see page 7, last paragraph). Strober et al. teach that said method can be used to treat autoimmune disease mediated by T cells or B cells (see page 5). Strober et al. do not teach use of the antigens recited in the claims to treat atherosclerosis. Hansson et al. teach that Ox LDL functions as an autoantigen in atherosclerosis (see abstract). Sima et al. also teach that Ox LDL functions as an autoantigen in atherosclerosis (see sixth line from bottom). Sima et al. also teach that autoantibodies bind modified/derivatives of LDL (eg. glycated LDL or HNE-Lys). Resch et al. teach that autoantibodies bind modified/derivatives of LDL (eg. HNE-LDL or MDA-LDL). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Strober et al. teach compositions of autoimmune antigens and the use of said compositions to treat autoimmune disease while Sima et al., Resch et al. and Hansson et al. teach that modified LDL/Ox LDL are autoantigens or bind autoantibodies involved in atherosclerosis. One of ordinary skill in the art would have been motivated to do the aforementioned because Strober et al. teach that said treatment can be used to treat "any other autoimmune disease now known or discovered in the future" (see page 5, lines 20,21).

13. No claim is allowed.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The

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examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON  
PRIMARY EXAMINER  
GROUP 1800



Ron Schwadron, Ph.D.  
Primary Examiner  
Art Unit 1644